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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,310	01/21/2000	Gary Stephenson	7922	5677

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EXAMINER

KRASS, FREDERICK F

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/489,310	Applicant(s) STEPHENSON, GARY	
	Examiner Frederick F. Krass	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-15, 17-20 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-15, 17-20 and 22-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **Status of Case**

The extended prosecution history of this case is regrettable. A new action over new art by the new examiner follows hereinunder. Accordingly, this action is NON-FINAL.

All previous rejections and requirements are expressly withdrawn.

### **Anticipation Rejection**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 11-15, 17-20 and 22-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohl et al (USP 3,681,091).

The prior art discloses fruit juices which comprise 0.1 to 5 weight percent linear sodium or potassium polyphosphates having 14 to 100 repeating units (preferably 16 to 37). See the passage spanning col. 1, lines 60 to col. 2, line 9, and see also the passage spanning col. 2, line 51 to col. 2, line 6. Note also that the working examples comprehensively test polyphosphates having various specific chain lengths within that range. (See especially Table VIII and XI following cols. 13 and 14). The juices are acidic

in nature, having low pH's. See Example 24 at col. 13 (orange juice having pH 4.10) and col. 15, line 11 (apple cider having pH 3.6, which anticipates "about" 3.5 as recited by instant claim 18). The prior art compositions do not appear to contain any substantial quantities of calcium, fluoride or orthophosphate. Regarding the requirement of instant claims 13, 19, 25 and 30, it is self-evident that fruit juices such as apple and orange already contain, inherently and naturally, sweeteners within the range of 0.1 to 20 percent by weight.

Regarding claims 11-15, 17-20 and 22, the prior examiner's position that "information" (presumably in the form of label) imparts no patentable weight is in fact the official position of the United States Patent Office on this issue. The indicia on the products in Miller and Gulack were functionally related to the article they were placed on, e.g. in Gulack the printed matter and the circularity of the band were interrelated, so as to produce a new product useful for "educational and recreational mathematical" purposes. The case at hand is different. The addition of a new set of instructions into a known kit does not interrelate the kit in the same way as the numbers interrelated with the band. In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly not be able to produce the desired result. Here, the printed matter ("information") in no way depends on the kit, and the kit does not depend on the printed matter. All the printed matter does is teach a new use for an existing product. As the Gulack court pointed out, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." In re Gulack, 703

F.2d 1381, 1387 (Fed. Cir. 1983). If the Patent Office were to adopt Applicant's position, anyone could continue patenting a product indefinitely provided that they added a new instruction an existing product. This is not the outcome envisioned by the Gulack court.

Regarding claims 23-31, the recited "method for treating dental erosion" requires only that the beverage be "orally administered" to a mammal, which would occur in the prior art when the user consumed the beverage. Where a treatment preamble is recited, the phrase "in need thereof" must appear in the body of the claim to require administration to a particular individual requiring such treatment. See Jansen v. Rexall Sundown, Inc., 342 F.3d 1329 (C.A. Fed (Ind.)(2003). Accordingly, to overcome this rejection, the instant claims must be amended to read --- A method for treating dental erosion, comprising orally administering to a mammal in need thereof ---

2) Claims 11-14 and 22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaffar et al (USP 5,017,362).

The prior art discloses oral care compositions, including mouthwashes, comprising 0.1 to 7 weight percent linear sodium polyphosphates having 2 to 125 repeating units (col. 2, lines 54-60) and 0.1 to 5 weight percent sweetener (col. 7, lines 23 and 24). The compositions have a specified lower pH limit of about 4.5 (col. 4, lines 59) and are used to inhibit calculus formation (col. 1, lines 13 et seq), the underlying cause of dental erosion. It is the position of the examiner that a mouthwash is a "beverage", where that term is interpreted as broadly as reasonable, consistent with Applicant's specification. Note also that, although the prior art compositions contain a

fluoride-ion source, they are not excluded from the scope of the instant claims. This is because the instant specification defines "substantially free" of fluoride to mean less than 0.1 percent by weight (see page 7, line 6 therein), and the prior art contains the fluorine compound in amounts as low as 0.005 percent (col. 4, line 19 of the prior art).

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 15, 17 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffar et al in view of Kohl et al.

The primary reference has been discussed in the "Anticipation" section above and differs from the instant claims insofar as it does not specify the chain length of the polyphosphates used therein, other than to teach that they should have somewhere between 2 and 125 repeating units (col. 2, line 56). It is known, however, that medium-chain polyphosphates (i.e. those having 14-100, and preferably 16-37 repeating units), are preferable to long chain polyphosphates because the former have better solubility and viscosity. This is illustrated by the secondary reference teachings at col. 2, lines 10-22. Accordingly, it would have been obvious to have used medium-chain

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polyphosphates in the primary reference compositions, motivated by the desire to obtain improvements in solubility and viscosity, which are well-known in the art, as illustrated by the secondary reference.

2) Claims 11-14 and 22-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffar et al in view of Bahouth et al (USP 3,894,147).

The primary reference has been discussed in the "Anticipation" section above. In the interest of completeness of prosecution, it will be assumed, purely *arguendo* and for the purposes of this particular rejection only, that a mouthwash is not a "beverage".

It is well-known in the art that anti-calculus active agents can be orally delivered by any of a number of functionally equivalent therapeutic forms, including liquid dentrifices, mouthwashes and beverages. See col. 2, lines 4-14 of the secondary reference, which differs from the instant claims insofar as the active ingredient is a monomeric dialkyl phosphate, rather than a sodium polyphosphate as claimed instantly.

It would have been obvious to have delivered the anti-calculus polyphosphate active agents of the primary reference mouthwashes in any of a variety of known alternative forms, e.g. in beverages, since such alternative forms are art-recognized equivalents as taught by the secondary reference. One would be motivated to use beverages in particular for any of a number of reasons, e.g. to obtain better compliance in pediatric applications due to the more appealing taste.

3) Claims 15, 17 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffar et al in view of Kohl et al, the combination being considered further in view of Bahouth et al.

The primary and secondary references, and the motivation for combining them, have been discussed in subsection "1)" of the "Obviousness" section supra. Again, in the interest of completeness of prosecution, it will be assumed, purely *arguendo* and for the purposes of this particular rejection only, that a mouthwash is not a "beverage". It is well-known in the art that anti-calculus active agents can be orally delivered by any of a number of functionally equivalent therapeutic forms, including liquid dentrifices, mouthwashes and beverages. See col. 2, lines 4-14 of the tertiary reference, which differs from the instant claims insofar as the active ingredient is a monomeric dialkyl phosphate, rather than a sodium polyphosphate as claimed instantly.

It would have been obvious to have delivered the anti-calculus polyphosphate active agents of the mouthwashes suggested by the combined teachings of the primary and secondary references in any of a variety of known alternative forms, e.g. in beverages, since such alternative forms are art-recognized equivalents as taught by the tertiary reference. One would be motivated to use beverages in particular for any of a number of reasons, e.g. to obtain better compliance in pediatric applications due to the more appealing taste.



### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;  
Tuesday: 10-6:30PM;  
Wednesday: off;  
Thursday: 10-6:30PM; and  
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Marianne, can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

